UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MARK A. CORBAN, individually and on behalf of all others similarly situated,	*	
Plaintiffs,	*	
v.	*	Civil Action No. 14-cv-10201-IT
SAREPTA THERAPEUTICS, INC.; CHRIS GARABEDIAN; SANDY MAHATME; and ED KAYE,	*	
Defendants.	*	

MEMORANDUM & ORDER

March 31, 2015

I. Background

This putative federal securities class action lawsuit challenges statements and omissions concerning a biopharmaceutical company's drug candidate for the treatment of a rare disease. Plaintiffs allege that Sarepta Therapeutics, Inc. ("Sarepta") and Individual Defendants Chris Garabedian, Sandy Mahatme, and Ed Kaye violated section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and Rule 10b–5, 17 C.F.R. § 240.10b–5, promulgated thereunder, and that the Individual Defendants also violated section 20(a) of the Exchange Act. Presently before the court is Defendants' Motion to Dismiss Plaintiffs' Amended Complaint [#42]. Because the court finds that Plaintiffs have not adequately alleged any actionable misstatements or omissions, Defendants' motion to dismiss is allowed.

II. Facts[1]

The putative class members purchased the securities of Sarepta during the period of July 10, 2013 through November 11, 2013 (the "Class Period"). Consolidated Class Action Compl. ¶ 1 [#39] ("Compl."). During the Class Period, Sarepta was focused on advancing eteplirsen—its leading drug candidate for the treatment of Duchenne muscular dystrophy ("DMD")—through the Food and Drug Administration's ("FDA") approval process. Id. ¶¶ 14, 21. DMD, a rare genetic disease caused by a mutation in the dystrophin gene, results in the absence of dystrophin—a protein necessary for muscle function. Id. ¶ 14. Currently, no approved disease-modifying therapies exist for DMD. Id. ¶ 16.

As the Complaint explains, the first step toward accelerated approval of a drug is the FDA's acceptance for consideration of a New Drug Application ("NDA"). Id. ¶¶ 36-37. The FDA's decision to accept an NDA is not based on the merits of the product, but is a threshold determination of whether there exists sufficient data to examine the product and permit substantive review. Id.

A. Eteplirsen's Clinical Trials

Eteplirsen allows the cells of certain DMD patients to produce truncated but functional dystrophin. Id. ¶ 47. To test its safety and efficacy, Sarepta evaluated eteplirsen in a randomized, double-blind study (Study 201). In Study 201, Sarepta enrolled twelve boys aged seven to thirteen years who had a genotype amenable to treatment. Id. ¶ 48. These patients were randomized to one of three treatments weekly—placebo, eteplirsen 30 mg/kg, and eteplirsen 50 mg/kg. Id. After 24 weeks, all patients receiving the placebo were then given eteplirsen at 30

[1] Because the issues analyzed here arise in the context of a motion to dismiss, this court presents the facts as they are related in Plaintiffs' Complaint, see Trans-Spec Truck Serv., Inc. v. Caterpillar, Inc., 524 F.3d 315, 321 (1st Cir. 2008), and construes those facts in the light most favorable to Plaintiffs, see Pettengill v. Curtis, 584 F. Supp. 2d 348, 362 (D. Mass. 2008) (quoting Rodriguez-Ortiz v. Margo Caribe, Inc., 490 F.3d 92, 96 (1st Cir. 2007)).

mg/kg or 50 mg/kg. Id. After 28 weeks, all patients were rolled over into a long-term study (Study 202), which continued to follow the product's efficacy and safety. Id. These studies were conducted as part of Sarepta's Phase IIb clinical trials. Id. ¶ 18.

The success or failure of a clinical trial can be measured by whether the trial meets a pre-specified endpoint or outcome and by the statistical significance of its results. Id. ¶ 27. For eteplirsen, the pre-specified endpoint concerned the change in the percent of dystrophin-positive fibers present in muscle biopsies. Id. ¶ 49. By restoring semi-functional dystrophin production in DMD patients, Sarepta hypothesized that eteplirsen could restore or prevent further deterioration of muscle weakness. Id. To evaluate the product's effectiveness, Sarepta collected muscle biopsies from all patients before treatment, at Week 12 from the four patients in the 50 mg/kg cohort and two placebo-treated patients, at Week 24 from the four patients in the 30 mg/kg cohort and two placebo-treated patients, and again from all patients at Week 48. According to these trials, eteplirsen treatment of 12 weeks or longer resulted in increased dystrophin production in all patients. Id.

An important secondary endpoint tied to the product's clinical efficacy, however, was the six-minute walk test (6MWT). Id. ¶ 50. This test measures how far a patient can walk in six minutes. Id. In Sarepta's Phase IIb clinical trials, there was no statistically significant difference in how far patients who received 30 mg/kg of eteplirsen could walk in six minutes as compared to patients on placebo. Id. Similarly, there was no statistically significant difference when combining the results from the patients on 30 mg/kg and 50 mg/kg of eteplirsen and comparing those results to those of placebo patients. Id. Plaintiffs allege that to avoid these adverse results, Sarepta excluded data from two patients in the 30 mg/kg cohort who had lost walking ability during the trials. Id.

B. Plaintiffs' Investigation

Conducting its own investigation into Sarepta's Phase IIb clinical trials, Plaintiffs provide an opinion from its own expert as well as information from three former Sarepta employees. First, Plaintiffs provide the opinion of Richard A. Guarino, a medical doctor who has worked in the pharmaceutical industry for over forty years and is purported to be an expert on the FDA's standards and regulations for drug approval. Id. ¶ 52. Dr. Guarino, after reviewing the available data regarding the eteplirsen trials, concludes that the trials suffered from significant problems such that FDA approval of an NDA was highly unlikely. Id. ¶ 53. This conclusion is based on the following: (1) that the patient population established by Sarepta was too small to lay the groundwork for a Phase III trial program, never mind approval based only on a Phase II study, and (2) that Sarepta deviated from the intent-to-treat guidelines by excluding two patients who lost ambulation, which biased the efficacy and safety results of the trial, and whose inclusion resulted in no meaningfully statistical significant differences versus placebo. Id.

As concerns the latter point, the Complaint details the FDA's policy regarding the collection, maintenance, and inclusion of clinical study data, including information on subjects who withdraw from clinical studies. Id. ¶ 43. As explained by the FDA in its Guidance for Sponsors, Clinical Investigators, and IRBs: Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials, "FDA law and regulations recognize that a complete and accurate risk/benefit profile of an investigational product depends upon the data from every subject's experience in the clinical trial." Id. ¶ 45. Removal of already collected data—including data from subjects who have withdrawn from the study—would undermine the scientific and ethical integrity of the research. Id. ¶ 46. For these reasons, the FDA has long advised against so called "informative censoring," recommending instead an "intent-to-treat"

approach in which the tester analyzes data related to all subjects that the investigator intended to treat while utilizing different approaches for the interpretation and imputation of missing data. Id. ¶ 45.

In addition, Plaintiffs allege facts provided by three former Sarepta employees. Confidential Witness 1 ("CW 1"), who previously served as Senior Clinical Director at Sarepta, recalls from company meetings that Defendant Chris Garabedian—President, CEO, and a director of Sarepta during the relevant time period—chose the efficacy endpoints for eteplirsen and tended to push his own plans through without generating consensus within the company. Id. ¶ 56. CW 1 also explained how Sarepta proceeded without first obtaining a Special Protocol Assessment, a tool by which the sponsor of a clinical trial and the FDA meet to discuss the sponsor's proposed protocols and reduce any agreements to writing that becomes part of the administrative record. Id. ¶ 25. Through this mechanism, the sponsor can incorporate any recommendations from the FDA into their trials. Id. ¶ 57. According to CW 1, Sarepta took on tremendous risk in foregoing a Special Protocol Assessment, as the FDA had never before approved a drug in eteplirsen's class. Id. This, combined with the trial's small study group, hampered the likelihood of FDA approval of eteplirsen. Id.

Confidential Witness 2 ("CW 2") and Confidential Witness 3 ("CW 3") added similar information concerning Defendant Garabedian's "hands-on" approach. According to CW 2, Sarepta's former Associate Director of Business Development, Garabedian was informed on every facet of the company, including the progress of eteplirsen, as he "micro-managed" and "weighed in on everything, down to the type of letterhead on the stationary." Id. ¶ 60.[2] CW 3

[2] In connection with their motion, Defendants submitted a declaration from Eileen Faucher to controvert facts alleged in the Complaint. See Decl. Eileen Faucher [#43-2]. For purposes of this motion to dismiss, however, the court considers the allegations made in the complaint and not Ms. Faucher's assertions in her declaration.

also describes Garabedian as very "hands on" in designing and interpreting the clinical trials and data for eteplirsen. Id. ¶ 64. Additionally, CW 2 relates how none of the companies approached by Sarepta to form a joint-venture decided to pursue such an arrangement because of those companies' various concerns over eteplirsen and Sarepta's ability to obtain FDA approval. Id. ¶ 61.

C. False and Misleading Statements Alleged in the Complaint

As discussed further below, Plaintiffs allege misstatements and omissions from ten separate disclosures made by Defendants during the Class Period concerning etiplirsen's test results and data set, Defendants' discussions with the FDA in July 2013, and the adverse implications of a failed Phase 3 trial of a drug developed by two other companies for the treatment of DMD.

III. Discussion

Defendants move to dismiss the Complaint for failing to (1) allege any actionable misstatements or omissions, and (2) establish a strong inference of scienter as required by the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4(b)(2).

A. Elements of a Rule 10b-5 Claim and Pleading Standards

Under section 10(b) and Rule 10b-5,[3] a claim of securities fraud has six elements: (1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation. ACA Fin. Guar. Corp. v.

[3] "Section 10(b) of the Securities Exchange Act of 1934 forbids the 'use or employ, in connection with the purchase or sale of any security . . . , [of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors.'" Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 318 (2007) (quoting 15 U.S.C. § 78j(b)). SEC Rule 10b-5 implements this section by declaring it unlawful to, among other actions, "make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made . . . not misleading." Id. (quoting 17 CFR § 240.10b–5).

Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008). At the motion to dismiss stage, the court "accept[s] well-pleaded factual allegations in the complaint as true and view[s] all reasonable inferences in the plaintiffs' favor." Id. To survive a motion to dismiss, a complaint must include factual allegations that, taken as true, demonstrate a plausible claim for relief. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555–58 (2007). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

In securities fraud cases, the plaintiffs must also meet the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) and the PSLRA. Under Rule 9(b), plaintiffs must plead fraud with particularity. Fed. R. Civ. P. 9(b). Under the PSLRA, plaintiffs must "'specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading.'" ACA Fin. Guar. Corp., 512 F.3d at 58 (quoting 15 U.S.C. § 78u-4(b)(1)).

Additionally, "[t]he PSLRA also separately imposes a rigorous pleading standard on allegations of scienter." Id. To overcome a motion to dismiss, plaintiffs must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." § 78u-4(b)(2). In the First Circuit, "a plaintiff may satisfy the scienter requirement with a showing of either conscious intent to defraud or a high degree of recklessness." ACA Fin. Guar. Corp., 512 F.3d at 58 (quotation marks and citations omitted).

B. Material Misstatements and Omissions

"To prevail on a § 10(b) claim, a plaintiff must show that the defendant made a statement that was 'misleading as to a material fact.'" Matrixx Initiatives, Inc. v. Siracusano, 131 S. Ct. 1309, 1318 (2011) (quoting Basic Inc. v. Levinson, 485 U.S. 224, 238 (1988) (emphasis in

original)). "A fact is material when there is a substantial likelihood that a reasonable investor would have viewed it as significantly altering the total mix of information made available." Fire and Police Pension Ass'n v. Simon, 778 F.3d 228, 240 (1st Cir. 2015) (quotation marks and citations omitted).

The mere possession of material non-public information, however, does not create a duty to disclose it. Hill v. Gozani, 638 F.3d 40, 57 (1st Cir. 2011). A duty to disclose, rather, is created when a corporation speaks, as Rule 10b-5 requires disclosure when "necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading," 17 C.F.R. § 240.10b–5. "Nevertheless, this obligation has its limits: It 'does not mean that by revealing one fact about a product, one must reveal all others that, too, would be interesting, market-wise'; a company must reveal only those facts 'that are needed so that what was revealed would not be so incomplete as to mislead.'" Hill, 638 F.3d at 57 (quoting Backman v. Polaroid Corp., 910 F.2d 10, 16 (1st Cir. 1990)).

1. Claims based on eteplirsen's trial results and data set

Plaintiffs point to Defendants' statements concerning the comprehensiveness of eteplirsen's trials, the definitiveness and robustness of eteplirsen's trial results, and the correlation between eteplirsen-induced dystrophin and a clinical benefit. See Pls.' Corrected Mem. Law Opp'n Defs.' Mot Dismiss, 12 [#49] ("Opp'n"). For example, at the start of the Class Period, on July 10, 2013, Defendant Garabedian made a number of statements in a presentation he gave to analysts and investors at the JMP Securities Healthcare Conference. During the presentation, Garabedian described eteplirsen's trial results, stating that the product's positive results showed "a high level of consistency" and that "every single patient" has shown stable walking times. Compl. ¶ 66. Defendant Garabedian stated further that the patient data from

eteplirsen's trials, in Sarapta's view, was "clear evidence that the dystrophin we are producing . . . is resulting in this stabilization or essentially halting of the progression of this disease in terms of ambulation." Id.

During a July 24, 2013 conference call, Garabedian stated that the dystrophin-positive fibers at Week 48 were "leading to stabilization in all of our available ambulatory patients." Id. ¶ 71. He stated further that "[w]e have a very rich clinical outcome data set, we believe, based on the Six-minute walk benefit now through week 84." Id. During that same call, an analyst questioned Garabedian whether such a small patient data set would make the FDA comfortable with the predictability of a reasonably likely clinical benefit. Id. Garabedian responded by stating that "it's not about the size of the study but it's about the treatment effect," while referencing another source discussing that "clinical outcomes that are robust in a small study can form the basis of a full approval." Id. Garabedian also stated that "I think that we believe that our dystrophin analysis is robust and is consistent across genotypes." Id.

Likewise, on August 8, 2013, Garabedian further stated that "we have a very strong basis that the dystrophin that we're producing is validating the clinical outcomes that we're seeing and should be acceptable as a surrogate end point under the accelerated approval pathway." Id. ¶ 75. And in an August 8, 2013 press release, the company stated that "eteplirsen-treated patients evaluable on the 6-minute walk test (6MWT)" demonstrated stabilization in walking ability compared to a placebo/delayed treatment cohort, while reiterating in that press release as well as during a September 9, 2013 investor conference that the trial's results were "consistent," "stable," and "robust." Id. ¶¶ 74, 84.

Plaintiffs argue that these statements were misleading because eteplirsen's Phase IIb trials utilized a population of only ten to twelve patients. They contend that the statements of a

correlation between dystrophin and a clinical benefit were false and misleading because Defendants omitted that two patients, out of twelve, lost ambulation entirely despite showing a significant increase in dystrophin levels, which undermined the correlation between dystrophin and the stabilization of walking ability. Id. ¶¶ 67, 82. Plaintiffs allege that Defendants excluded data from those two patients in discussing eteplirsen's trial results, the inclusion of which would have caused the results to show no statistically significant improvements in walking ability. Id. ¶ 67.

The court finds that the challenged statements were not materially misleading because Sarepta repeatedly disclosed—both before and during the Class Period—the fact that it had excluded data from those two patients.[4] For instance, before the start of the Class Period, in an October 3, 2012 press release disclosing eteplirsen's trial results, the company disclosed the trial results and its interpretations of those results with respect to both the intent-to-treat (ITT) population as well as with respect to a modified intent-to-treat population (mITT), that is, the population with the two patients excluded. See Decl. Vito Supp. Mem. Law. Supp. Defs.' Mot.

[4] In considering this motion, the court "must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." Tellabs, Inc., 551 U.S. at 322. "Courts are permitted, in some instances, to consider on a Rule 12(b)(6) motion documents that were not attached to the complaint." Foley v. Wells Fargo Bank, N.A., 772 F.3d 63, 74 (1st Cir. 2014). "[T]hese 'narrow exceptions' . . . include 'documents the authenticity of which are not disputed by the parties; . . . documents central to plaintiffs' claim; or . . . documents sufficiently referred to in the complaint.'" Id. (quoting Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993)). In connection with their motion to dismiss, Defendants submitted a number of documents in support of their arguments, see Docket Entry #44, which the parties have treated as properly before the court. Some of these documents, such as Sarepta's public filings with the U.S. Securities and Exchange Commission, are clearly ones in which the court may take judicial notice. To the extent, however, that any document does not fall within the narrow exceptions articulated by the First Circuit, the parties have had ample opportunity to object or present additional material pertinent to the motion, see, e.g., Decl. William B. Federman Supp. Pls.' Mem. Law Opp'n Defs.' Mot Dismiss [#47] (attaching exhibits), and, therefore, the motion is properly treated as one for summary judgment under Federal Rule of Civil Procedure 56. See Fed. R. Civ. P. 12(d).

Dismiss, Ex. 15 at 1-2 [#44] ("Vito Decl."). As to the ITT population, the company explained that it found a statistically significant treatment benefit for eteplirsen-treated patients who received 50 mg/kg of the drug weekly, but that "[t]here was no statistically significant difference between the cohort of patients who received 30 mg/kg weekly of eteplirsen and the placebo/delayed treatment cohort." Id. at 1. Following a chart depicting the ITT results, the company then provided the following information:

> Modified Intent-to-Treat (mITT)
>
> The 6MWT results were further analyzed using the mITT population which excluded two patients who were randomized to the 30 mg/kg weekly eteplirsen cohort who showed signs of rapid disease progression within weeks after enrollment and were unable to perform measures of ambulation beyond 24 weeks. This mITT population consisted of 10 patients (4 eteplirsen-treated patients receiving 50 mg/kg weekly, 2 eteplirsentreated patients receiving 30 mg/kg weekly, and 4 placebo/delayed-treatment patients).

Id.

Moreover, at the start of the Class Period, on July 10, 2013, the company gave an investor presentation in which it disclosed that the results for eteplirsen's Phase IIb study depicted in the presentation were based on an mITT population. See id. Ex. 24 at 18-21. And again, on August 8, 2013, the company issued a press release promoting the publication of a peer-reviewed article in the Annals of Neurology that described eteplirsen's clinical trial results. See Compl. ¶ 74. This peer-reviewed article described the results for both the ITT and mITT populations and provided a rationale for the use of the mITT approach. See id., Ex. 2. On a conference call held on that same day, an analyst discussed the two patients who had been excluded from the study, stating that he "was struck by the fact that they had a similar increase to the mean in terms of the dystrophin that was put back into their muscles." Id. ¶ 75. In response, Defendant Kaye—Senior Vice President and Chief Medical Officer of Sarepta—stated that

"once that muscle is fibrotic, we can't repair it and based on all of the data it appears that it was too late for these boys." Id.

These are but some examples of the disclosures provided by the company, which make clear that the market and scientific community was informed that the company was basing its more favorable results on an mITT population. That the company defended use of the mITT population and cast its trial results in a positive light does not detract from this disclosure, as "[a] defendant does not have a duty to cast the descriptions of its business in the most negative light." Coyne v. Metabolix, Inc., 943 F. Supp. 2d 259, 269 (D. Mass. 2013). Accordingly, claims that the company made material misstatements or omissions based on Sarepta's use of the mITT population must fail.

Likewise, claims based on Defendants' statements touting the strength of eteplirsen's data set also fail. As stated above, the market was clearly aware of the company's use of the mITT population and Plaintiffs thus cannot allege that Defendants presented factually inaccurate information to the market. Moreover, many of the challenged statements consist of interpretations of the company's data, which constitute non-actionable expressions of opinion unless Plaintiffs can allege that (1) the company's opinions were both objectively and subjectively false, i.e., that the person holding the opinion did not subjectively believe in it, (2) self-embedded facts within the opinion are untrue, or (3) "material facts about the [opinion holder's] inquiry into or knowledge concerning a statement of opinion" were omitted." Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, No. 13-435, 2015 WL 1291916, at *6, 8 (S. Ct. Mar. 24, 2015). Here, Plaintiffs have not made such a showing.

2. Claims based on Defendants' discussions with the FDA

Plaintiffs allege that Defendants did not adequately disclose that the FDA had raised questions and/or concerns in July 2013 regarding Sarepta's dystrophin quantification methodology. In a July 24, 2013 press release, Sarepta announced its plans to submit an NDA for the approval of eteplirsen. Compl. ¶ 70. The press release provided that

> The decision to submit an NDA for eteplirsen in 2014 is based on productive interactions with the FDA in a meeting that occurred this week. That meeting was a follow-up to the FDA's review of two recently submitted summary documents that included data on dystrophin and clinical outcomes from the existing eteplirsen studies. The FDA stated in pre-meeting comments that the Agency is "open to considering an NDA based on these data for filing." The Agency, however, requested additional information related to the methodology and verification of dystrophin quantification. Sarepta believes the requests from the Agency can be addressed and incorporated into an NDA submission in the first half of 2014.

Vito Decl. Ex. 6. In the press release, Sarepta also stated that it was "encouraged by the feedback from the FDA and believe that data from our ongoing clinical study merits review by the Agency and will be sufficient for an NDA filing," but that "the exact timing of the submission will be dependent on further discussions and agreement with the FDA on the information needed for an acceptable filing." Id. (internal quotation marks omitted). Moreover, Sarepta explained that

> The Agency would not commit to declaring dystrophin an acceptable surrogate endpoint under the CFR 314 Subpart H Accelerated Approval pathway prior to an NDA filing and commented that a decision by the Agency to file "the NDA would not indicate that we have accepted dystrophin expression as a biomarker reasonably likely to predict clinical benefit. A filing would only indicate that the question merits review, and that we deem the data to be reviewable."

Id.

In August 2013, Sarepta reiterated this information. For example, on an August 8, 2013 conference call, Garabedian stated that the FDA's "feedback is particularly encouraging because

it recognizes that our Phase IIB study data set is sufficient for the FDA to consider a filing." Compl. ¶ 75. During an August 13, 2013 presentation, Garabedian characterized the news that the FDA would consider an NDA filing as the "type of information that every company hopes for which is an encouraging sign from the FDA that a mid-stage trial, a phase II study is strong in enough to consider for an NDA filing." Id. ¶ 80.

Thereafter, on November 12, 2013, the company issued a press release announcing the FDA's current position that an NDA filing for eteplirsen would be premature and disclosing excerpts from the FDA's most recent pre-meeting comments, including that "[s]ince our last meeting, our concern about the shortcomings of your current quantification methods has grown." Id. ¶ 90. That same press release disclosed that the FDA had informed the company that it "believe[s] that a placebo-controlled trial would be the most likely method for developing interpretable evidence of efficacy for eteplirsen" and that it "would like to discuss the perceived barriers to conducting such a trial with you." Id.

Plaintiffs claim that Defendants did not adequately disclose that the FDA had raised concerns regarding its dystrophin quantification methodology at the July 2013 meeting. Based on the FDA's pre-meeting comments explaining the reversal of its position, Plaintiffs posit that Sarepta's disclosures made after the company's July 2013 meeting with the FDA were materially misleading because the FDA's pre-meeting comments released in November 2013 demonstrate that the FDA had communicated to Sarepta that the information it had developed to date was insufficient. Plaintiffs argue that this information was known to the company prior to November 12, 2013, pointing to Garabedian's statements made during a conference call held on that same date, in which he stated that "the agency has reiterated their demand for a placebo-controlled study." Id. ¶ 91 (emphasis in original). Plaintiffs also argue that any "perceived barriers" that

Sarepta had raised would have predated the November 2013 pre-meeting comments, evidencing that the FDA had previously expressed a preference for a placebo-controlled study.

Plaintiffs' arguments, however, are undermined by the company's disclosures made in its July 24, 2013 press release announcing its decision to submit an NDA for eteplirsen. In the press release, the company disclosed that "[t]he FDA stated in pre-meeting comments that the Agency is 'open to considering an NDA based on these data for filing,'" but immediately qualified that disclosure by stating that "[t]he Agency, however, requested additional information related to the methodology and verification of dystrophin quantification." Vito Decl. Ex. 6. After expressing its opinion that these requests could be addressed and incorporated into an NDA submission in the first half of 2014, the company further explained that "the exact timing of the submission will be dependent on further discussions and agreement with the FDA on the information needed for an acceptable filing." Id. The company, moreover, warned that statements about "the potential filing and acceptance of an NDA for eteplirsen" was "subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement," including that "the FDA may determine that our NDA submission for eteplirsen does not qualify for filing or that substantial additional data is required for accelerated or other approvals." Id.

Plaintiffs do not appear to argue that any statement in the July 24, 2013 press release was false, but rather dispute the extent to which the company disclosed the FDA's issues concerning an NDA filing for eteplirsen. The press release, however, not only announced that the company had decided to submit an NDA in 2014 and quoted the FDA's pre-meeting comments that it was "open to considering an NDA based on these data for filing," but it informed the public that the FDA had requested additional information related to the methodology and verification of dystrophin quantification and that the company would have further discussions with the FDA on

the information needed for an acceptable filing. Defendants were under no duty, at that time, to delve into the FDA's specific concerns over the sufficiency of eteplirsen's potential NDA application, at least absent their making of statements that would contradict such concerns. See Simon, 778 F.3d at 244 (stating that "[t]here must be some room for give and take between a regulated entity and its regulator"). Moreover, the company's statements that it was encouraged by the feedback and believed its data would be sufficient for a filing constituted an expression of opinion, which as described above is not actionable unless Plaintiffs show that these beliefs were not subjectively held. Thus, based on the above, the company did not mislead the public in its July 24, 2013 press release.

Plaintiffs further argue that, in light of the FDA's comments released in November 2013, the company went too far and materially misled investors in statements made after July 24, 2013. Plaintiffs challenge, for instance, statements asserting that eteplirsen's "Phase IIB study data set is sufficient for the FDA to consider a filing," Compl. ¶ 75, and that the FDA's feedback was the "type of information that every company hopes for which is an encouraging sign from the FDA that a mid-stage trial, a phase II study is strong in enough to consider for an NDA filing," id. ¶ 80. Plaintiffs argue that these statements were materially misleading because, based on the FDA's pre-meeting comments released in November 2013, "it is evident that the FDA had expressed concerns about both the Phase II data set and its clinical outcomes during the July 2013 meeting." Opp'n at 22 (emphasis in original).

The challenged statements, however, though couched in more optimistic language after July 24, 2013, do nothing more than reiterate what had already been disclosed in the July 24, 2013 press release. Such statements are not materially misleading merely because Plaintiffs "seem to take issue with . . . the general 'rosy' picture that defendants attempted to paint about

the results." See Bristol Pension Fund v. Vertex Pharm. Inc., 12 F. Supp. 3d 225, 237–238 (D. Mass. 2014). "[I]t is not illegal for a company to paint a positive or optimistic picture when disclosing information to investors," as long as such a picture is not misleading. Id. at 238.

Plaintiffs' allegation that "it is evident" that the FDA expressed concerns to the company in July 2013 such that Defendants' post-July 2013 statements were misleading is made upon information and belief and is based on the company's release of some of the FDA's pre-meeting comments in November 2013. The FDA's pre-meeting comment released in November 2013 that "[s]ince our last meeting, our concern about the shortcomings of your current quantification methods has grown," see Compl. ¶ 90, without more, does not shed light on the magnitude of the FDA's concern in July 2013 or whether, for instance, the FDA thought that the company could alleviate such concern by providing additional information. Likewise, the FDA's comments that it "believe[s] that a placebo-controlled trial would be the most likely method for developing interpretable evidence of efficacy for eteplirsen" and that it "would like to discuss the perceived barriers to conducting such a trial with you," id., also lack sufficient detail. Although these comments show that the issue of a placebo-controlled trial was likely discussed during the July 2013 meeting, Plaintiffs' allegations do not reveal any specifics about this discussion, such as how strongly the FDA had expressed its preference for a placebo-controlled trial. In light of the company's disclosures concerning the July 2013 meeting—that the FDA had "requested additional information related to the methodology and verification of dystrophin quantification" and that "the FDA may determine . . . that substantial additional data is required for accelerated or other approvals," Vito Decl. Ex. 6,—the court finds that Plaintiffs have not met their pleading burden under the PSLRA.

Lastly, Plaintiffs contend that Defendants' statements emphasizing the feedback and guidance that the company had received from the FDA was materially misleading because the company omitted that it had elected to conduct its Phase IIb trials without first obtaining a Special Protocol Assessment. See Compl. ¶¶ 73, 76, 82, 86. This assertion, however, falls far short from alleging a material misstatement or omission. As the Complaint explains, in rare instances, a sponsor can seek accelerated approval for a drug and may submit an NDA before clinical trials are complete. Id. ¶ 36. Here, the Complaint admits that "Sarepta has held meetings with the FDA to explore the potential for accelerated approval of eteplirsen based on dystrophin levels as a surrogate endpoint." Id. ¶ 51. Due to the unmet need that could be solved by eteplirsen, Sarepta frequently consulted with the FDA. In making the challenged statements, the company merely acknowledged the consultation that they were receiving from the FDA. In light of the above, the fact that Sarepta had not obtained a Special Protocol Assessment was not one which the company was required to reveal. See Hill, 638 F.3d at 57.

3. Claims based on the failed Phase 3 trial of drisapersen

During an October 17, 2013 presentation, Defendants Garabedian and Kaye addressed the failed Phase 3 trial of drisapersen, a drug developed by Prosensa and GlaxoSmithKline which similarly worked to increase dystrophin to achieve a clinical benefit documented by the six-minute walk test. They stated that the results "underscore[d] how important it is to have a chemistry that does not have dose-related toxicity that may prohibit a dose that is active enough to produce a clinical effect." Compl. ¶ 85. Defendants asserted further that, due to its different chemical structure, eteplirsen may be given in doses "that are five-to eightfold greater than those doses studied in the disapersen trials." Id. In making these statements, Defendants distinguished eteplirsen from drisapersen based on the former's chemical structure and ability to be tested in

higher doses, which, according to Defendants, produced a "robust and consistent response." Id. Plaintiffs argue that these statements misled the public.

Plaintiffs contend that the correlation between eteplirsen and a clinical benefit was undermined by the failed Phase 3 trial of drisapersen and that Defendants downplayed the adverse implications of that failed test. Specifically, Plaintiffs take issue with Defendants' statements distinguishing eteplirsen by the fact that it can be administered in doses "five-to eightfold greater" than the doses studied in the drisapersen trials. Plaintiffs assert that the failed drisapersen trials did not occur because of the ineffectiveness of that drug's dosage but rather because of the disconnect between the increased expression of dystrophin and clinical efficacy for drisapersen, and that "[t]his was the precise problem facing Sarepta, which Sarepta hid through the exclusion adverse data." Opp'n at 18-19.

But, as previously stated, the company repeatedly disclosed its use of the mITT population—it did not "hide" any purported disconnect between the increased expression of dystrophin and clinical efficacy. Plaintiffs' claim, therefore, boils down to their disagreement with Defendants' interpretation of drisapersen's failed trial results and how those results related to eteplirsen's ongoing trials. As explained above, such opinions are non-actionable unless Plaintiffs allege that Defendants did not subjectively believe them, that self-embedded facts within the opinion were untrue, or that material facts related to Defendants' inquiry into or knowledge concerning the opinion were omitted, see Omnicare, Inc., 2015 WL 1291916, at *6, 8, which they have not done.

C. Section 20(a) Claims

Plaintiffs' claims against the Individual Defendants under Section 20(a) of the Exchange Act, 15 U.S.C. § 78t, must also fail because Plaintiffs have not adequately pled a claim under

section 10(b) and Rule 10b-5. See ACA Fin. Guar. Corp., 512 F.3d at 67 ("The plain terms of section 20(a) indicate that it only creates liability derivative of an underlying securities violation.").

IV. Conclusion

For the foregoing reasons, Defendants' Motion to Dismiss Plaintiffs' Amended Complaint [#42] is ALLOWED and the Consolidated Class Action Complaint [#39] is hereby dismissed.

IT IS SO ORDERED.

Date: March 31, 2015

/s/ Indira Talwani
United States District Judge